



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/731,867

12/09/2003

Carl D. Wahlstrand

1023-336US01

6722

28863 7590 08/05/2008
SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER

REIDEL, JESSICA L

ART UNIT

PAPER NUMBER

3766

NOTIFICATION DATE

DELIVERY MODE

08/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplaw.com

Office Action Summary	Application No. 10/731,867	Applicant(s) WAHLSTRAND ET AL.	
	Examiner JESSICA REIDEL	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-22,28-31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-22,28-31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2008 has been entered. Claim 2 has been newly cancelled. Claims 11, 23-27 and 32 were previously cancelled. Claim 35 is new and has been added. Claims 1, 3-10, 12-22, 28-31 and 33-35 are currently pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 2, 2008 has been acknowledged and is being considered by the Examiner.

Specification

3. The specification contains reference to commonly owned patent applications without application numbers and/or without stating the current status of each application. For example, the disclosure references commonly-assigned application numbers 10/730,873, 10/731,881 and 10/731,638, which have since been issued as U.S. Patent Numbers 7,242,982, 7,392,089 and 7,212,864, respectively. The Examiner respectfully requests that this information be updated (including and in addition to the amendments previously made to the specification on January 3, 2008) and it is also requested that any other referenced applications, that have since issued or since been abandoned, are also updated accordingly in response to this Office Action. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. In view of the response filed June 3, 2008, the 35 U.S.C. 112, second paragraph rejections applied against Claims 12 and 13 in the Final Rejection of April 4, 2008 have been withdrawn.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

6. ***Claims 1, 3-10, 12-22, 28-31 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys et al. (U.S. 6,308,101) (herein Faltys) in view of Probst et al. (U.S. 2003/0017372) (herein Probst).*** As to Claims 1, 3-6, 10, 13, 18, 22, 29 and 35, Faltys expressly discloses a partitioned IMD 160 comprising a plurality of interconnected modules (i.e. an implantable cochlear stimulator (ICS) 112' and an implantable speech processor/power (SP/PWR) unit 162). Faltys specifies that the SP/PWR unit 162 may comprise a metallic hermetic housing of titanium, stainless steel, or other similar material that is compatible with body tissue (see Faltys Figs. 1E, 3A and 3B and column 12, lines 17-55). Additionally, the ICS 112' module comprises an analog chip, read as a therapy delivery element U1 and a gate array chip, read as control electronics U2, both the therapy delivery element U1 and control electronics U2 being within a hermetic ceramic housing of the ICS 112' module. Therapy delivery element U1 includes circuits for providing stimulation currents, voltage regulation, and bi-directional telemetry modulation and control electronics U2 controls the delivery of the stimulation current and the bi-directional telemetry (see Faltys Fig. 8B, column 17, lines 57-67 and column 18, lines 1-7). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If a prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, since the IMD 160 of Faltys is implantable beneath the scalp of a patient and since the therapy delivery element U1 provides current for driving implantable electrodes of an electrode array 114, the therapy delivery element U1 is capable of delivering stimulation therapy to a brain of a patient. Furthermore, Faltys expressly discloses that the partitioned IMD 160, as previously discussed, "may be applied to other implantable neural or muscular stimulation devices, or other implantable devices", in addition to its disclosed cochlear application (see Faltys column 20, lines 65-67 and column 21, lines 1-10). The IMD 160 of Faltys further comprises a coil 172 embedded within a silicone rubber encasing mold 174. The Examiner considers the encasing mold 174 of Faltys synonymous with Applicants claimed "overmold" since the mold 174 is

Art Unit: 3766

“formed so as to adhere to the sides” of the SP/PWR unit 162 and the ICS 112' module and because, upon inspection of Faltys Figs. 3A and 3B, the mold 174 appears to “at least partially encapsulate” each of the modules and the modules are horizontally distributed at respective locations of the mold 174. The Examiner also considers the modules as being “separately encapsulated” by the mold 174 since the modules are separated or partitioned (see Faltys Figs. 3A and 3B).

Faltys discloses the claimed invention, as previously discussed, except that it is not specified that the overmold 174 be formed such that a surface of the overmold is concave along at least two axes prior to manipulation of the IMD 160 such that the surface is adapted to be implanted proximate to a cranium of the patient and to conform substantially to the cranium. Probst, however, teaches an IMD 10 (i.e. a neurostimulator, pacemaker, defibrillator) housing comprising opposed major sidewalls 62, 64 of a contoured shape (see Probst Figs. 1-4 and 6-8) and an inner power source module 12 housing 14, also having opposed sidewalls 16, 18 of a contoured shape (see Probst Fig. 1) such that areas of the body, such as the skull, do not have to be invasively and/or unnecessarily excavated in order to facilitate implantation of the IMD. Specifically, the IMD 10 of Probst comprises a housing manufactured such that opposing surfaces conform substantially to an arc, where at least a first surface is concave along multiple axes and the second opposing surface is convex and distal from the first surface and the implantation site (i.e. the cranium). The housing components of Probst conform substantially to an arc (see Probst Figs. 7-8 and page 3, paragraphs 36-42) prior to manipulation of the IMD 10 such that the surfaces are adapted to be implanted proximate to a cranium, to conform substantially to the cranium (see Probst Abstract, pages 1-2, paragraphs 2-4 and paragraphs 21-24). IMD 10 of Probst also comprises housing 14 of module 12, identical to that of the housing of the entire IMD (see Probst page 1, paragraphs 16-19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold 174 and the housings modules 162, 112' of the partitioned IMD 160 taught by Faltys, such that a surface of each is concave along multiple axes as taught by Probst, such that the overmold 174 and the modules 162, 112' conform substantially to an arc, prior to manipulation of the IMD 160, in order to provide an improved IMD 160 adapted to be implanted proximate the cranium of

Art Unit: 3766

the patient, to conform substantially to the cranium and further such that the IMD 160 may be easily implanted without undo excavation of the implant site.

The previously modified Faltys reference discloses the essential features of the claimed invention except that it is not specified that the concave surface of the overmold 174 be concave along two *perpendicular* axes (emphasis added). The Examiner, however, considers it to be conventional and well known in the art of implanted devices for an outer surface of a device to be concave along at least two perpendicular axes, such that the surface is adapted to be implanted proximate/adjacent to and facing a specific anatomical structure, in that the surface conforms substantially to the shape of the specific anatomical structure by substantially conforming to the shape of a convex arc. The Examiner cites *Trabucco et al. (U.S. 5,243,977) (herein Trabucco)*, *Sanchez-Zambrano (U.S. 5,895,414)*, *Gray (WO 92/20402)* and *Bardy et al. (U.S. 2002/0042634) (herein Bardy '634)* as evidence in the conventionality of such features as they are known in the art. Trabucco discloses a pacemaker including a casing for housing a pulse generator to be used for stimulating, by direct contact, the epicardium and myocardium of the heart. Specifically, a direct transmission of electric pulses, generated by the pacemaker, is achieved from the pacemaker's casing to the heart. Trabucco teaches that the pacemaker's casing may have several shapes, and in one embodiment, a surface of the casing 1000 is "biconcave", or concave along at least two perpendicular axes, such that the surface is adapted to be implanted proximate/adjacent to a portion of the epicardium, in that the surface conforms substantially to the shape of the portion of the epicardium by substantially conforming to the shape of a convex arc (see, for example, Trabucco Fig. 13, Abstract, column 1, lines 5-10, column 3, lines 40-67, column 4, lines 1-35 and column 8, lines 5-9). Gray also discloses a pacemaker comprising a housing 10 or umbrella-shaped container, read as an overmold 18, that each have at least one surface that is concave along at least two perpendicular axes, such that the surface is advantageously adapted to be implanted proximate/adjacent to a portion of the heart, in that the surface conforms substantially to the shape of the portion of the heart by substantially conforming to the shape of a convex arc (i.e. the housing 10 or overmold are cup-shaped or hemispherical in shape) (see, for example, Gray Fig. 1C and Fig. 2, page 8, lines 1-8, page 10, lines 33-38 and page 11, lines 1-14).

Sanchez-Zambrano and Bardy '634 both disclose an IMD (e.g., a pacemaker or ICD) for subcutaneous positioning within a patient comprising a housing having a surface that is concave along at least two perpendicular axes, such that the surface is adapted to be implanted proximate/adjacent to and facing a specific anatomical structure (e.g., a rib/ribs of the patient), in that the surface conforms substantially to the shape of the specific anatomical structure by substantially conforming to the shape of a convex arc. Sanchez-Zambrano teaches that a pacemaker having such a concave surface "is anatomically shaped to respect natural curvatures of the bones in a patient's chest" in order to provide significant advantages (i.e. increased comfort, decreased stress etc.) (see Sanchez-Zambrano, entire document). Bardy '634 teaches that such a housing may be non-malleable or malleable and Bardy '634 further specifies that a surface of the housing of the ICD may having more than one non-uniform radii of curvature throughout the housing "such that it can be shaped closer to the shape of the ribs" or such that it "mimics the natural curvature of the ribcage" in order to provide significant advantages (i.e. increased comfort, decreased stress etc.). Bardy '634 also discloses that it may be preferable to modify the length, width, depth, and/or radii of the housing in its entirety, or only a portion thereof, "in order to accommodate a variety of sized patient recipients" (see, for example, Bardy '634 Figs. 19-21, page 3, paragraphs 46 and 52, page 6, paragraphs 65 and 70-72, pages 7-8, paragraphs 79-80, 83 and 86-87, page 9, paragraphs 93 and 95, page 10, paragraphs 100-102, page 12-14, paragraphs 120-124 and 135-138 and page 15, paragraphs 153-155). Accordingly, as previously discussed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the overmold 174 and the housings modules 162, 112' of the partitioned IMD 160 taught by Faltys, such that a surface of each is concave along multiple axes as taught by Probst, such that the overmold 174 and the modules 162, 112' conform substantially to an arc, prior to manipulation of the IMD 160, in order to provide an improved IMD 160 adapted to be implanted proximate the cranium of the patient, to conform substantially to the cranium and further such that the IMD 160 may be easily implanted without undo excavation of the implant site. It additionally would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the concave overmold 174 taught by Faltys in view of Probst, such that the concave surface of the overmold 174 is concave along two perpendicular axes, since it was known in the art that such a modification would provide an

Art Unit: 3766

improved IMD 160 having an advantageous concave surface that is adapted to be implanted proximate/adjacent to and facing the cranium, in that the surface conforms substantially to the shape of the cranium by substantially conforming to the shape of a convex arc.

7. As to Claims 7, 9, 19 and 21, the modified Faltys reference discloses the claimed invention, as previously discussed, except that it is not specified that the arc be within a range from 4.5-9.5 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to make the arc taught by Faltys in view of Probst be within a range from 4.5 to 9.5 centimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. As to Claims 8 and 20, the previously modified Faltys reference discloses the claimed invention, as discussed above, except that it is not specified that the arc be approximately equal to 7 centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the arc 7 centimeters, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. As to Claim 14, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a control module that includes control electronics. In particular, Faltys expressly discloses that the SP/PWR unit 162 may include an analog front end (AFE) circuit U4, which is a microphone control circuit 240, a gate array chip U3, and a processor chip U5 (see, for example, Faltys Fig. 8A, column 16, lines 46-67 and column 17, lines 27).

10. As to Claims 15, 16 and 33, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a power source module that may include a rechargeable lithium-Ion (Lion) battery 216, or other types of batteries or replenishable power sources, such as ultracapacitors (see, for example, Faltys column 3, lines 62-67, column 4, lines 1-65, column 5, lines 1-18, column 8, lines 45-67, column 9, lines 32-48 and column 15, lines 49-65). The previously modified Faltys reference discloses the claimed invention, as discussed above, except it is not specified that the battery of the IMD 160 have a wound coil construction or a foil pack construction. It would

Art Unit: 3766

have been obvious to one having ordinary skill in the art at the time the invention was made, however, to modify the battery of Faltys in view of Probst to have either a wound coil construction or a foil pack construction, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See *In re Leshin*, 125 USPQ 416.

11. As to Claim 17, in addition to the arguments previously presented, Faltys expressly discloses that the module comprising the metallic housing, specifically the SP/PWR unit 162, is a recharge module including a recharge coil 172 for inductively receiving energy (see, for example, Faltys Figs. 3A and 3B and column 12, lines 17-55).

12. As to Claims 12 and 28, in addition to the arguments previously presented, Faltys indicates that a ceramic, or equivalent material, is used for the case material of the ICS 112' module, to facilitate magnetic coupling through the case. Faltys further specifies that "a metal header 115 is hermetically sealed to one end of the ceramic case", thus the Examiner considers the housing of the ICS 112' as "metallic". Overmold 174 does not encapsulate the metal header 115 portion of the ICS 112' module housing (see Faltys Figs. 3A and 3B and column 12, lines 17-41).

13. As to Claims 30, 31 and 34, in addition to the arguments previously presented, since the overmold 174 of Faltys is made of a flexible silicone rubber, the overmold 174 "is configured to allow relative motion between the plurality of interconnected modules" (i.e. ICS 112' and SP/PWR unit 162) (see Faltys Figs. 3A and 3B and column 12, lines 17-41).

Response to Arguments

14. Applicant's arguments filed June 3, 2008, with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Byland et al. (U.S. 5,456,698) disclose a modular pacemaker comprising a container at least partially encapsulated by a "shroud", read as an overmold.

Art Unit: 3766

Kolenik (U.S. 3,926,198) discloses a cardiac pacer comprising a plurality of interconnected modules including a circuitry unit/module that comprises a metallic housing in electrical contact with a metallic overmold of the pacer.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
July 28, 2008

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766
July 31, 2008